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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,134	03/11/2004	Gregory H. Altman	032794-054911-CIP	6963
50828	7590	11/14/2011		
DAVID S. RESNICK NIXON PEABODY LLP 100 SUMMER STREET BOSTON, MA 02110-2131			EXAMINER NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			11/14/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/800,134	ALTMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DAVID NAFF	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 1,2 and 4-49 is/are pending in the application.
- 5a) Of the above claim(s) 32-49 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,2 and 4-31 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/5/10</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been  
5 withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/09 has been entered.

The submission submitted remarks in response to a final rejection of 12/4/08 and advisory action of 5/18/09, and did not amend the claims.

The claims in an amendment after final rejection have been entered as indicated by the advisory action.

Claims in the application are 1, 2 and 4-49.

10 Claims 32-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/6/06.

Claims examined on the merits are 1, 2 and 4-31.

### ***Claim Rejections - 35 USC § 103***

15 Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al (7,285,637), and if necessary in view of Li et al (6,303,136) and Takezawa et al (5,736,399).

The claims are drawn to a fabric comprising one or more yarns wherein the yarn comprises one or more sericin-extracted fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, and that are biocompatible and non-randomly organized. The yarn promotes ingrowth of cells and is biodegradable.

20 Armato et al disclose producing non-woven silk fibroin fabrics for use as a cell culture scaffold by degumming silk fibroin to remove sericin, treating with formic acid to break disulfide bonds, and removing the formic acid by evaporation to obtain the fabric (Example 1, col 4, lines 34-50). The breaking of disulfide bonds results in chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells (col 4, lines 21-25). Armato et al further disclose that it is known to use silk fibroin as a cell culture matrix (col 2, lines 4-17), and

that textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers in order to obtain a flexible fabric (col 2, lines 20-22).

Li et al disclose attaching cells to a filamentous matrix that can be made from various materials including silk (col 2, line 49 and col 4, line 18).

5 Takezawa et al disclose using a silk mesh as a culture carrier (col 5, lines 56-60).

It would have been obvious to omit breaking disulfide bonds as disclosed by Armato et al if the result of breaking the bonds is not desired, i.e. providing chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells since Armato et al disclose that it is possible to merely use degummed silk fibroin fibers to obtain a flexible fabric. It is clear from Armato et al (col 2, lines 20-22) that fabric can be obtained  
10 without breaking the bonds, and omitting breaking the bonds would have been expected to simplify the process and be an advantage. To substitute the advantage of simplification for the advantage of obtaining chain fragments having cellular recognition sites promoting attachment and growth of cells would have been within the ordinary skill of the art. Li et al disclosing attaching cells to a matrix that can be made of silk and Takezawa et al using a silk mesh as a culture carrier without a requirement for breaking bonds, if needed, would have further suggested that breaking  
15 bonds as disclosed by Armato et al can be omitted if the function of breaking bonds is not desired. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The parent application does not antedate Armato et al since the presently claimed invention is not disclosed in the parent application.

### ***Response to Arguments***

20 In regard to a 131 Declaration previously submitted and held not to antedate Armato et al because exhibits A and B did not disclose a fabric, the response urges the exhibits disclose a fabric as the term is used in the instant claims, defined in the specification. However, the six cord construct containing six parallel cords in the fourth paragraph on the first page of Exhibit B is not a fabric when the term fabric is given its art recognized meaning. The paragraph bridging columns 6 and 7 of patent 6,902,932, which issued from parent application 10/008,924, discloses

the same six parallel cords. However, the parent application like Exhibit B nowhere recites that the six parallel cords constitute a "fabric". The description of forming a fabric occurred for the first time in the instant application, which is a continuation-in-part (CIP) of the parent application. The description of forming a fabric in the present application does not have support in the parent application and Exhibits A and B. Exhibits A and B relate to an invention described in the parent application bridging columns 6 and 7, and not to an invention that is a fabric as described in the instant application. The amendment refers to Figure 4A of the present application as showing fabrics. While paragraph 0052 states that Fig. 4A shows images of multiple yarn and fabric forms, none of the specific images are described as a fabric. Images i-vi are described as various types of braids, image vii is described as a yarn, images viii-xi are described as twisted yarns, and image xii is described as two level cabled yarns. Braids and yarns are not fabric. There is not support in the parent application or Exhibits A and B that braids and yarns of Fig. 4A are fabric. Fig 4A is not present in the parent application. Fabric is shown by Fig. 2B and Figs. 20A-20C, which are different structures than shown by images i-xii of Fig. 4A. The amendment asserts that structures of Exhibits A and B fall within the definition of fabric occurring in the present application. However, this is a matter of individual interpretation. In any event, fabric and its definition in the present application are not mentioned in the parent application and Exhibits A and B. The concept of a fabric occurred in the instant CIP application, not in the parent application and Exhibits A and B. At the time of Exhibits A and B and filing the parent application, none of the described structures were considered to be a fabric.

In regard to the 103 rejection, the amendment urges Armato et al teach disulfide bonds are broken to promote attachment and growth of cells, whereas the claims recite "wherein said yarn promotes ingrowth of cells around said fibroin fibers". Therefore, the ordinary skilled artisan would not have been motivated to omit breaking of the disulfide bonds as disclosed by Armato et al to produce the instant invention. However, Armato et al disclose (col 2, lines 4-6) the use of silk fibroin as a cell culture matrix is already known. Therefore, it would have been obvious breaking disulfide bonds disclosed by Armato et al is not essential for using silk fibroin fabrics as a scaffold or carrier for culturing cells. Culturing cells on silk fibroin fabrics without breaking disulfide bonds would have been further

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suggested by Li et al disclosing attaching cells to a filamentous matrix that can be made from various materials including silk, and Takezawa et al disclosing using silk mesh as a culture carrier. When cell culture on the fabric is possible without breaking disulfide bonds, the motivation to omit breaking the bonds is to save the expense and time required to break the bonds, and provide simplification. When the entire disclosure of Armato et al is considered, and if needed the disclosures of Li et al and Takezawa et al, it becomes obvious that while breaking disulfide bonds can be used to promote cell attachment, fabric formed of sericin-extracted fibroin fibers can function as a scaffold or carrier for cell culture without breaking the disulfide bonds. The use of yarn in making fabric is well known, and it would have been obvious to use a yarn containing the fibers of Armato et al in place of only the fibers to make fabric.

The response urges the filamentous matrix of Li et al formed of silk is a non-degradable silk suture matrix, which is unsuitable for the present invention. However, the rejection is not based on using the filamentous matrix of Li et al, but on using the fabric of Armato et al as a cell culture carrier. A fabric made of silk fibroin fibers would have been expected to function as a cell culture carrier irrespective of whether the fabric is biodegradable or non-degradable.

The response urges Takezawa et al requires further manipulation of the culture medium or carrier itself to promote cell adherence. However, the manipulation does not involve breaking disulfide bonds, and the instant claims do not exclude manipulation of the type disclosed by Takezawa et al.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

DMN  
11/7/11